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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,725	02/06/2002	Wayne Kindsvogel	01-04	8714

7590 09/01/2005

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,725

Applicant(s)

KINDSVOGEL, WAYNE

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 9 and 11-24 are canceled.
Claim 1 has been amended.
2. Claims 1-8 and 10 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

5. The rejection of claims 9-10 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn in view of the amendments to the claims.
6. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph for lack of enablement is withdrawn in view of the amendment to the claims.
7. The rejection of claims 1 and 3-8 under 35 U.S.C 102(e) as being anticipated by Theill et al (US Patent 6,774,106) is withdrawn in view of the amendments to the claims.
8. The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Theill et al (US Patent 6,774,106) in view of Gross et al (WO 00/40716) is withdrawn in view of the amendments to the claims.

New Grounds of Objections/Rejections

9. Claims 1-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The response filed 6/20/2005 has introduced NEW MATTER into the claims. As presently amended, claim 1 recites a method for inhibiting the proliferation of tumor cells comprising endogenous BCMA and TACI comprising administering to the tumor cell a composition that comprises an antibody component that binds both BCMA and TACI at an epitope within a polypeptide consisting of amino acid residues 105 to 166 of SEQ ID NO:4. The response points to page 40 line 9 of the specification as filed for support for the presently amended claim limitations. The as filed specification at page 40 line 9 does not provide adequate written support for the presently amended claims. Although page 40 as filed discloses an anti-BCMA-TACI multispecific antibody that binds both BCMA and TACI for the treatment of tumor cells, the specification does not disclose or contemplate an anti-BCMA-TACI multispecific antibody binds both BCMA and TACI at an epitope within a polypeptide consisting of amino acid residues 105 to 166 of SEQ ID NO:4. The specification discloses that the epitope consisting of amino acids 105 to 166 of SEQ ID NO:4 is specific to the TACI protein (see page 6, line 33 to page 7 line 2). The BCMA sequence of SEQ ID NO:2 does not appear to contain the epitope consisting of amino acids 105 to 166 of SEQ ID NO:4. Further, the specification at pages 16-17,

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which discloses antibodies that can bind both BCMA and TACI ("anti-BCMA-TACI dual reactive antibodies") does not disclose the epitope consisting of amino acids 105 to 166 of SEQ ID NO:4 as the epitope of an antibody that binds both BCMA and TACI.

Additionally, for the reasons discussed above, there is inadequate written support for a method for inhibiting the proliferation of tumor cells comprising endogenous BCMA and TACI comprising administering to the tumor cell a composition that comprises an antibody component that binds both BCMA and TACI at an epitope within a polypeptide consisting of amino acid residues 110 to 118 of SEQ ID NO:4.

Instant claims 1-8 and 10 now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in presently amended claim 1, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER